

46851-12

2/25/2016

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

February 25, 2016

Samuel Payne
President
Certol International LLC
6120 East 58th Ave.
Commerce City, CO 80022

Subject: Notification per PRN 98-10 – Additional Marketing Language
Product Name: ProSpray Wipes
EPA Registration Number: 46851-12
Application Date: Dec. 29, 2015
Decision Number: 511454

Dear Mr. Payne:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 for the above referenced product. The Antimicrobials Division (AD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action requested falls within the scope of PRN 98-10.

The label submitted with the application has been stamped "Notification" and will be placed in our records.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

If you have any questions, you may contact Tom Luminello at (703) 308-8075 or via email at luminello.tom@epa.gov.

Sincerely,

A handwritten signature in black ink that reads "Tom Luminello".

Jacqueline Hardy, Product Manager 34
Regulatory Management Branch II
Antimicrobials Division (7510-P)

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Certol[®] International

[Kills [99.9% of] [viruses] [and] [bacteria] [in 3 minutes]]

ProSpray™ wipes

[Surface Disinfectant] [/] [Cleaner] [Towelettes]

["One-Step"] [Cleaner] [/] [Disinfectant] [/] [Deodorizer]

[The descriptive terms below are to be used, as applicable, depending on the microorganisms listed in the Effective Against Section.]

[Tuberculocidal] [,] [[Virucidal]*] [,] [Bactericidal] [,] [Fungicidal]

[Kills Staphylococcus aureus - MRSA HA [in three minutes]]

Active Ingredients

o-phenylphenol	0.647%
o-benzyl-p-chlorophenol	0.070%
Inert Ingredients	99.283%
Total	100.000%

E.P.A. Reg. No. 46851-12
E.P.A. Est. No. 46851-CO-003

[Lot #] [and] [expiration date] [printed on container]

[_____] [Pre-moistened] [Towelettes]
[[_____ in. x _____ in.] [(_____ cm x _____ cm)]]
[Reorder No: _____]
Net Contents: [_____] [lbs.] [_____] [oz.]

NOTIFICATION
Date Reviewed: 2-25-16
Reviewed By: PK

Keep Out of Reach of Children

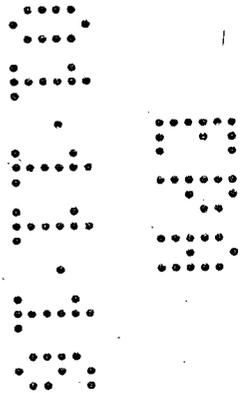
CAUTION

[See other panels for additional precautionary statements.]

[THIS IS NOT A SKIN WIPE]



[THIS IS NOT A BABY WIPE]



[PRODUCT BARCODE:] [+H816 _____]

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FIRST AID:

IF SWALLOWED: Call a Poison Control Center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a Poison Control Center or doctor. Do not give anything by mouth to an unconscious person. Have the product container or label with you when calling a Poison Control Center or doctor or going for treatment.

IF INHALED: Move person to fresh air. If person is not breathing, call 911 or an ambulance, and then give artificial respiration, preferably mouth-to-mouth if possible. Call a Poison Control Center or doctor for further treatment advice.

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a Poison Control Center or doctor for treatment advice.

HOTLINE NUMBER: In case of an emergency call toll free 1-800-535-5053.

PRECAUTIONARY STATEMENTS:

Hazardous to humans and domestic animals.

CAUTION: Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

USER SAFETY REQUIREMENTS: Follow manufacturers' instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry. [Users must wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.]

[Listing of at least one of the following equipment/instruments/hard, non-porous surfaces on production labels are required. The last equipment/instrument/hard, non-porous surface listed will be preceded with the word "and".]

DESCRIPTION: ProSpray™ wipes are [non-woven] [,] [non-abrasive] [disposable] [towelettes] presaturated with ProSpray™ Disinfectant. [ProSpray™ wipes are [an effective ["one-step"] [cleaner] [and] [intermediate-level] [disinfectant] [according to the AOAC Use-Dilution Test]] [modified in the presence of 5% organic soil load] [and] [meets AOAC efficacy standards for hospital-use disinfectants.]] [This product [cleans] [,] [disinfects] [and] [deodorizes] [hard non-porous surfaces] [in one labor-saving step]]. [ProSpray™ wipes may be used in [healthcare,] [office,] [transport,] [commercial] [and] [home settings] [on] [vinyl,] [plastics,] [metals,] [floors,] [walls,] [counters,] [carts] [and] [bedside equipment.]]

[Choose one of the following directions based on packaging]

[a. Canister]

[TO OPEN PACKAGE: Open cap lid and pull up firmly using lid to remove the entire cap from canister. Remove protective seal. Locate wipe at the center of the roll and insert corner of wipe through opening in lid. Replace lid. Pull wipe up and slightly to the side. The next wipe pops up automatically. Always snap lid securely shut between uses to prevent moisture loss.]

[b. Soft Pack]

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[PREPARATION OF DISPENSER: Lift up tab and pull back to expose the entire opening. Do not remove Peel & Seal tab. Grasp exposed edge of towelette and pull out. Close Peel & Seal tab to prevent evaporation by returning it to its original position and press down firmly.]

[ProSpray™ wipes are effective against the following microorganisms on hard, non-porous surfaces when used as directed:]

[EFFECTIVE AGAINST:]

- [MYCOBACTERIUM TUBERCULOSIS VAR. BOVIS [(TB)]]**
- [STAPHYLOCOCCUS AUREUS]**
- [STAPHYLOCOCCUS AUREUS - MRSA HA]**
- [SALMONELLA ENTERICA]**
- [PSEUDOMONAS AERUGINOSA]**
- [[*]HIV-1 [(AIDS VIRUS)]]**
- [[*]HERPES SIMPLEX VIRUS TYPES 1 & 2]**
- [TRICHOPHYTON MENTAGROPHYTES [(FUNGUS)]]**

DIRECTIONS FOR USE:

IT IS A VIOLATION OF FEDERAL LAW TO USE THIS PRODUCT IN A MANNER INCONSISTENT WITH ITS LABELING.

[DO NOT USE AS A BABY WIPE.] [NOT FOR USE ON SKIN.] [DO NOT FLUSH WIPE.]
[Must not be used in hospital nurseries.]

[The following paragraph will be included in its entirety when the production label references healthcare use.]

ProSpray™ wipes are designed for use on hard non-porous surfaces. This product is not to be used as a terminal sterilant/high-level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high-level disinfection.

CLEANING: ProSpray™ wipes are an effective ready-to-use cleaning agent. [Occasional rinsing or wiping with [[a] damp cloth][soap and water] is recommended when [ProSpray™] wipes are used frequently on [floors][,][stainless steel][,][vinyl][and][other] [hard [non-porous] surfaces.]

FOR USE AS A ONE-STEP CLEANER/DISINFECTANT: Pre-clean heavily soiled areas. [ProSpray™ wipes may be used for this step.] [Discard used wipes after pre-cleaning.] Remove one or more fresh ProSpray™ wipes Disinfectant Towelette(s), unfold, wipe surface thoroughly. If areas are not heavily soiled, clean and disinfect with one wipe. All surfaces must remain visibly wet for 3 minutes.

CONTACT TIME:

[ONE MINUTE EXPOSURE:]

[HIV-1 [(AIDS virus)]] [,] [Herpes simplex virus types 1 & 2]

[THREE MINUTE EXPOSURE:]

[Mycobacterium tuberculosis var. bovis [(TB)]] [,] [Staphylococcus aureus] [,]
[Staphylococcus aureus - MRSA HA] [,] [Salmonella enterica] [,] [Pseudomonas aeruginosa] [,]
[Trichophyton mentagrophytes [(Fungus)]]

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[The following HIV instructions are to be included on production labels when claims against HIV are listed.]

ProSpray™ wipes kill HIV-1 on pre-cleaned environmental surfaces/objects previously soiled with blood/body fluids in healthcare settings or other settings in which there is an expected likelihood of soiling inanimate surfaces/objects with blood or body fluids, and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of human immunodeficiency virus Type-1 HIV-1 [(associated with AIDS)].

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV ON SURFACES OR OBJECTS SOILED WITH BLOOD OR BODY FLUIDS:

PERSONAL PROTECTION: When handling items soiled with blood or body fluids or when conducting procedures which might lead to contact with blood or body fluids, always wear items such as disposable gloves, gowns, masks and eye coverings.

CLEANING PROCEDURES: Blood and body fluids must be thoroughly cleaned from surfaces and objects before application of ProSpray™ wipes. [ProSpray™ wipes may be used for this purpose.]

DISPOSAL OF INFECTIOUS MATERIAL: Blood and other body fluids must be autoclaved and/or disposed of according to local regulations for infectious waste disposal.

CONTACT TIME: Allow surface to remain wet for one minute to kill HIV-1 [(AIDS Virus)] and Herpes simplex virus types 1 & 2. Use a three minute contact time for TB, Staphylococcus aureus, Staphylococcus aureus - MRSA HA, Salmonella enterica, Pseudomonas aeruginosa and Trichophyton mentagrophytes (Fungus).

STORAGE AND DISPOSAL:

Do not contaminate water, food or feed by storage or disposal.

PESTICIDE STORAGE: Store at room temperature in original container in an area inaccessible to persons unfamiliar with its use. Tightly close lid between uses to retain moisture.

PESTICIDE DISPOSAL: Do not reuse towelettes. Dispose of used towelette and empty container in regular trash. Do not flush used towelettes. To avoid waste, use all material in this container by application according to label directions. If wastes cannot be avoided, offer remaining product to a waste disposal facility or pesticide disposal program (often such programs are run by state or local governments or by industry).

[Choose one of the following disposal directions based on packaging]

[a. Canister]

[CONTAINER DISPOSAL: Non-refillable canister. Do not reuse or refill this canister. Offer for recycling if available or puncture and dispose of in a sanitary landfill or by procedures approved by state and local authorities.]

[b. Soft Pack]

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[CONTAINER DISPOSAL: Non-refillable container. Do not reuse or refill this container. Offer for recycling if available or puncture and dispose of in a sanitary landfill or by procedures approved by state and local authorities.]

[Optional Marketing Claims:]

[Lemon Scent.]

[Fresh Scent.]

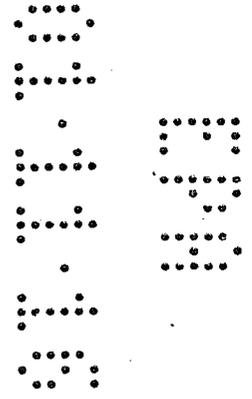
[AREAS OF USE:]

[NURSING, HOSPITAL AND HEALTHCARE SETTINGS:]

- [[Ambulatory Surgical Centers]](ASC)]
- [Anesthesia]
- [Cat Labs]
- [CCU]
- [Central Supply Clinics]
- [Clinics]
- [Dental Offices]
- [Dialysis]
- [Doctors' Offices]
- [Donation Centers [(Apheresis, Blood, Milk, Plasma, Semen)]]
- [Emergency Medical Settings]
- [Emergency Rooms]
- [Eye Surgical Centers]
- [Hospices]
- [ICU]
- [Isolation Areas]
- [Laboratory]
- [Laundry Rooms]
- [[Operating Rooms]](OR)]
- [Ophthalmic Offices]
- [Orthopedics]
- [[Out-patient Surgical Centers]](OPSC)]
- [Patient Care Areas]
- [Physical Therapy]
- [Radiology]
- [Reception Areas]
- [Recovery Rooms]
- [Rehabilitation]
- [Respiratory Therapy]
- [Surgery]
- [Waiting Room]

[OFFICE AND HOME SETTINGS:]

- [Libraries]
- [Manufacturing Facilities]
- [Office Buildings]
- [Public Facilities]
- [Cabinets]
- [Computers]
- [Counters]
- [Desks]



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[OFFICE AND HOME SETTINGS (continued):]

- [Doorknobs]
- [Fax Machines]
- [Filing Cabinets]
- [Garbage Cans]
- [Headsets]
- [Keyboards]
- [Public Telephones]
- [Railings]
- [Seats]
- [Sinks]
- [Tables]
- [Tabletops]
- [Telephones]
- [Work Stations]

[EMERGENCY SERVICES SETTINGS:]

- [Ambulances]
- [Police Cars]
- [Transport Vehicles]

[VETERINARY SETTINGS:]

- [Isolation Areas]
- [Veterinary Clinic]
- [Waiting Room]

[HEALTH CLUB FACILITIES AND GYMS:]

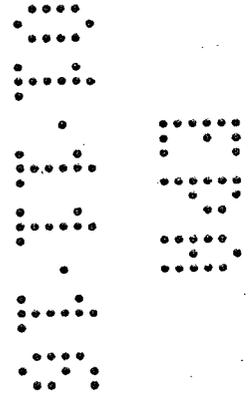
- [Gym Equipment]
- [Locker Rooms]
- [Reception Areas]
- [Showers]

[BATHROOMS:]

- [Basins]
- [Bathroom Fixtures]
- [Bathtubs]
- [Cabinets]
- [Countertops]
- [Doorknobs]
- [Faucets]
- [Glazed Tiled Walls]
- [Hampers]
- [Handles]
- [Handrails]
- [Showers]
- [Sinks]
- [Toilet [(Handle, Rim, Seats, Tank, Other Exterior Surfaces)]]
- [Urinals [(Exterior Surface)]]
- [Vanity Tops]

[TRANSPORT SERVICE SETTINGS:]

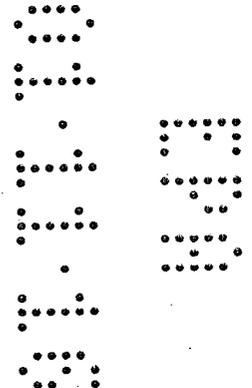
- [Fire Trucks]
- [School Buses]
- [Transport Vehicles]
- [Hard Plastic or Metal Flooring]
- [Seats]
- [Steering Wheel]
- [Walls]



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[HARD NON-POROUS SURFACES:]

- [Adapter Rings]
- [Bed Frame]
- [Bidet]
- [Booster Seats]
- [Brass]
- [Chrome]
- [Clean-up Carts]
- [Copper]
- [Crystal]
- [Culture Marble]
- [Cuspidors]
- [Drains]
- [Dressing Carts]
- [Drinking Fountains]
- [Enamel]
- [Examination Tables]
- [Fixtures]
- [Floors]
- [Non Wood Furniture]
- [Glass]
- [Glazed Ceramic Tile]
- [Glazed Porcelain Tile]
- [Laminate]
- [Lamps]
- [Light Switches]
- [Linen Carts]
- [Linoleum]
- [Litter Boxes]
- [Marlite]
- [Metal]
- [Metal Blinds]
- [Mirrors]
- [Outdoor Furniture]
- [Parquet]
- [Patient Chairs]
- [Pens]
- [Plastic]
- [Plastic Mattress Covers]
- [Portable Toilet]
- [Recycling Bins]
- [Remote Controls]
- [Resilient [(Ceramic)] Floor]
- [Sealed Granite]
- [Sealed Wood]
- [Sports Equipment]
- [Stainless Steel]
- [Stretchers]
- [Synthetic Marble]
- [Tin]
- [Tools]
- [Vinyl]



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[HARD NON-POROUS SURFACES (continued):]

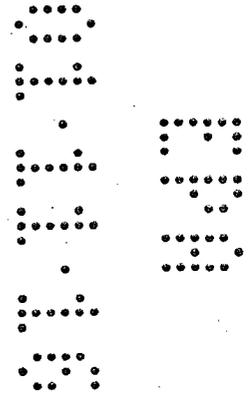
- [Wheelchairs]
- [Whirlpool Interiors]
- [Windows]

[HARD NON-POROUS USE SITES:]

- [Attic]
- [Automobile]
- [Basement]
- [Bathroom]
- [Bedroom]
- [Boat]
- [Cabin]
- [Camper]
- [Closet]
- [Den]
- [Dining Room]
- [Dorm]
- [Family][/][Living Room]
- [Garage]
- [Home]
- [Kitchen]
- [Laundry Room]
- [Locker]
- [Mobile Home]
- [Mudroom]
- [Pet Area]
- [Public Places]
- [Storage Area]
- [Studio]
- [Sunroom]
- [Tool Shed]
- [Workshop]

[HARD NON-POROUS PROFESSIONAL USE SITES:]

- [Blood Bank]
- [Clinic]
- [College]
- [Commercial Building]
- [Correctional Facilities]
- [Dental Office]
- [Doctors' Office]
- [Grocery Store]
- [Gymnasium]
- [Health Care Facility]
- [Health Club]
- [Hospital]
- [Hotel][;][Motel]
- [Kennel]
- [Laboratory]
- [Laundromat]
- [Military Installation]
- [Morgues]
- [Mortuaries]
- [Nursing Home]



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[HARD NON-POROUS PROFESSIONAL USE SITES (continued):]

- [Office Building]
- [Patient Room]
- [Pharmacy]
- [Public Places]
- [Recreational Center]
- [Restroom]
- [Shelter]
- [Sick Room]
- [Warehouse Club]

[ProSpray wipes are recommended for use in healthcare settings.]

[ProSpray wipes disinfectant towelettes are intended for use [on] [/] [in] medical [devices] [/] [settings].]

[ProSpray wipes [is]/[are] a multi-purpose [disinfectant][/][decontaminant] [cleaner] for use on hard, non-porous inanimate surfaces.]

[ProSpray wipes will effectively clean and disinfect, when used as directed, such items as [list]]

[FOR USE AS A DISINFECTANT ON PRECLEANED NON-CRITICAL MEDICAL DEVICES, INSTRUMENTS AND IMPLEMENTS: [Instruments must be thoroughly cleaned to remove excess organic debris [ProSpray wipes may be used for this step], rinsed and dried. Remove one or more fresh ProSpray wipes and apply to pre-cleaned surfaces, thoroughly wetting areas to be disinfected. Allow surfaces to remain visibly wet for 3 minutes at room temperature [(68°F / 20°C)]. Rinse instruments and wipe dry prior to use.]]

[Non-critical medical devices are items that come in contact only with intact skin.]

[ProSpray wipes are an effective method to clean against odor-causing organisms on hard, non-porous surfaces listed on this label.]

[Non-alcohol actives]

[Indicated for use when manufacturer's instructions direct that alcohol [on] [vinyls] [or] [plastics] must be avoided.]

[No bleach actives]

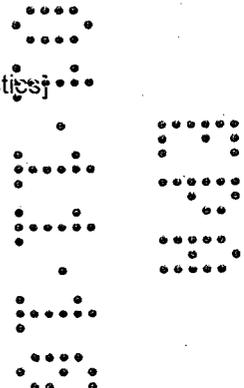
[Water-based intermediate-level disinfectant]

[Broad based material compatibility]

[Reduced toxicity for frequent users]

[Easy and convenient way to clean and disinfect]

[So surfaces are more than just clean, they are disinfected.]



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[The following statement is to be included on production labels when food contact areas or surfaces are listed:] [A thorough rinse with potable water is required for surfaces in direct contact with food.]

[This product contains [[phenolic] compounds, which are][ingredients that are] [naturally] [amber][amber to brown][brown] in appearance. [[As a result,] this product may develop similar coloration through the course of its normal shelf life.]]

[[Natural] [amber][amber to brown][brown] colored solution.]

[This product contains active ingredients that are [naturally] [amber][amber to brown][brown] in appearance.]

[The [amber][amber to brown][brown] color does not diminish the shelf life of the product.]

[[Soft porous material][and][white][light]colored surfaces] may experience cosmetic darkening of the surface over a prolonged period of use.]

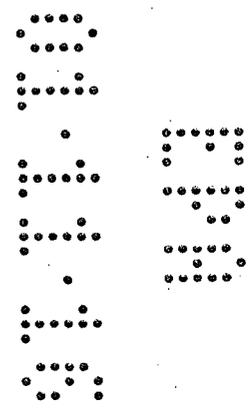
[Test this product in an inconspicuous location prior to use.]

Certol® International

A Limited Liability Company

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Toll-free: (800) 843-3343
www.certol.com

WIPES/EPA/TX05 10/15



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